## Remarks

Claims 1-19 and 43-48 are pending in the subject application. By this Amendment, Applicant has cancelled claims 3, 20-42, 46-58, and 60-62, added new claims 63-67, and amended claim 1, 6, 8, and 10. Support for the amendments can be found throughout the subject specification. Entry and consideration of the new claims presented herein is respectfully requested. Accordingly, claims 1-2, 4-19, 43-45, 59, and 63-67 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

### Restriction/Election

Examiner has requested clarification of the relationship between Sequence ID Numbers, cDNA clones named cor1.1-1.4, and microbial deposit numbers.

1. Sequence cor1.1 (nucleotide sequence SEQ ID NO 20 (Fig 10) and amino acid sequence SEQ ID NO 26 (Fig 4)) corresponds to deposit number DSM 12737:

2. Sequence cor1.2 (nucleotide sequence SEQ ID NO 21 (Fig 11) and amino acid sequence SEQ ID NO 27 (Fig 4)) corresponds to deposit number DSM 12738,

3. Sequence cor1.3 (nucleotide sequence SEQ ID NO 22 (Fig 12) and amino acid sequence SEQ ID NO 28 (Fig 4)) corresponds to deposit number DSM 12739 and

4. Sequence cor1.4 (nucleotide sequence SEQ ID NO 23 (Fig 13) and amino acid sequence SEQ ID NO 29 (Fig 4)) corresponds to deposit number DSM 12740.

In light of Examiner's restriction requirement, Applicants have amended the claims to the elected polynucleotides encoding for an enzyme of SEQ ID NO: 26 and related polynucleotides of SEQ ID NO: 20. In addition, Applicants respectfully submit that claim 59 should remain under examination as drawn to a polynucleotide with SEQ ID NO: 20 which codes for a codeinone reductase enzyme with the elected SEQ ID NO:26. Applicant has submitted a declaration in accordance with 37 C.F.R. § 1.132 to this effect.

## Specification/Drawings

Applicant has added an abstract as requested by Examiner. Examiner objected to the inclusion of drawings in Tables 1 and 2. Applicant has amended the specification to remove the drawings.

Examiner has stated that "Applicant's recital of nucleotide sequences longer than 10 base pairs, e.g., page 12 of the specification, requires a SEQ ID NO for each sequence." Applicant points the Examiner to review an amendment filed on January 2, 2002 which amends the specification and provides SEQ ID NOs for all polynucleotides on page 12. A copy of this amendment is attached for Examiner's convenience.

## Claim Objections

The Examiner objected to claim 3 due to informalities. Applicant cancelled claim 3 rendering Examiner's objection moot. Any other claims which may have similar informalities have been amended or cancelled.

## Claim Rejections - 35 U.S.C. §112

### Claims 10 and 46-48

Claims 10 and 46-48 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Examiner argued that claim 10 is "broadly drawn to any polynucleotide of any length and sequence derived from any source, which is complementary to any part of a codeinone reductase encoding nucleic acid of any length or sequence." Applicant has amended claim 10 to claim a polynucleotide encoding a codeinone reductase enzyme from *Papaver somniferum* where the polynucleotide sequence comprises SEQ ID NO: 20, where the polynucleotide sequence hybridizes under stringent conditions to complementary sequences of SEQ ID NO: 20, or where a polynucleotide is an allele of SEQ ID NO:20 and wherein the polynucleotide sequence codes for a codeinone reductase enzyme which has codeinone reductase activity. The Examiner's argument relating to a polynucleotide of any length derived from any source is moot in light of Applicant's amended claim 10.

Examiner argued that "with regard to sequences having less than 100% sequence identity and sequences that hybridize under "stringent" conditions, the breadth of these claims

encompasses unspecified base substitutions, deletions, additions, insertions, and combinations thereof without retaining function or with an inadequate function." Applicant's amended claim 10 claims polynucleotide sequences which code for a codeinone reductase enzyme which has codeinone reductase activity. Applicant's specification discloses activity relationships and methods of testing for codeinone reductase activity (See pages 17-18 and 21-22). Thus, Applicant's amended Claim 10 only claims sequences with less than 100% sequence identity or that hybridize under stringent conditions when these sequences code for codeinone reductase enzymes which have codeinone reductase activity. Examiner additionally argues that:

> the specification only provides guidance for the isolation of a polynucleotide encoding SEQ ID NO: 26 from poppy, and tobacco transformation therewith. No guidance is provided regarding sequence domains which would be conserved throughout the broadly claimed genus of sequences, wherein said sequence domains are associated with codeinone reductase activity.

In contrary, Applicants have provided guidance for the isolation of 6 different alleles which code for a codeinone reductase enzyme. At least four of the polypeptides resulting from the alleles have 95-96% homology. In addition, the amino acid sequence homology corresponding to the four different alleles (cor1.1-1.4) is disclosed in Figure 4. One skilled in the art can easily identify the conserved domains from Figure 4.

Examiner argued that:

> Hybridization to a given sequence, e.g., the codeinone reductase sequence, does not necessarily allow the making and using of the hybridizing sequence because sequences with very different function but only slightly different sequence will hybridize under even "high" stringency conditions.....Thus, if sequences are identified only by hybridization to known sequences that encode codeinone reductase activity, one cannot conclude on this basis alone that these sequences also will encode a protein having said activity without additional evidence of functionality or more knowledge of the particular structural features that are required for conferring this function.

Applicant's currently amended Claim 10 claims specific polynucleotide sequences which code for a codeinone reductase enzyme which have codeinone reductase activity. Thus, nucleotides claimed in the currently amended Claim 10 are assured of having enzyme activity.

Applicant's currently amended Claim 10 is fully enabled by the specification. Applicant has cancelled claims 46-48. Thus, Examiners rejections of claims 46-48 are moot in light of the cancellation. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112 is respectfully requested.

**Claim Rejections - 35 U.S.C. §112**

**Claims 17-19**

Claims 17-19 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. Examiner argued that:

> the specification does not provide any guidance regarding the composition of said plasmids, regarding any particular promoters, coding sequences, or other sequences. The specification does not even recite the claimed plasmids. Accordingly, one skilled in the art would not know how to make and/or use said plasmids.

Applicants respectfully submit that the application does enable claims 17-19 either through the disclosure of the specification or through the deposit at Deutsch Sammlung von Mikroorganismen und Zelkulturen GmbH (DSMZ). The particular plasmids claimed (pCAL-c, pGEM-T, and pFastBac1) are disclosed on page 4 of the specification. The sequence and methods of using these plasmids were known before the time of filing this application. Once one skilled in the art identified a particular nucleotide sequence encoding for the codeinone reductase enzyme, one skilled in the art would know how to use the pCAL-c, pGEM-T, and pFastBac1 plasmids to make a recombinant DNA construct. Examiner is invited to review a recent Federal Circuit case dealing with a similar issue in which the court stated:

> Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification. Accordingly, we hold that where, as in this case, accessible literature sources clearly provided, as of the relevant date, genes and their nucleotide sequences (here "essential genes"), satisfaction of the written description requirement does not require the recitation or incorporation by reference (where permitted) of such genes and sequences.

(See Falko-Gunter Falkner v. Stephan Inglis, Fed Cir. May 2, 2006)

In addition, Applicant has deposited SEQ ID NO: 20 as DSM 12737 with the DSMZ on March 16, 1999. DSMZ is an international depository which has the ability to comply with the

Budapest Treaty (See www.dsmz.de). This deposit was in accordance with the Budapest Treaty and this strain will be irrevocably and without restriction or condition be released to the public upon this issuance of a patent. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112 is respectfully requested.

**Claim Rejections - 35 U.S.C. §112**

**Claims 3 and 46-48**

Claims 3 and 46-48 are rejected under 35 U.S.C. §112, second paragraph, as failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Because Applicant has cancelled claims 3 and 46-48, Examiner's rejection is moot for these claims. Since the word stringent appears in amended claim 10 and new claim 51, Applicant has chosen to address Examiner's rejection. Examiner argues that:

> Applicant recites "stringent" conditions without defining such conditions. The ordinary skilled artisan would be unclear as to the precise meaning of the term: even "high stringency" is capable of separate and distinct meanings.

Applicants respectfully submit that "stringent conditions" is a term of the molecular biology art well understood to those skilled in the art. Applicant invites the Examiner to review the seminal text *Molecular Cloning: A Laboratory Manual* by Sambrook, Fritsch, and Maniatis (Second Edition 1989). Chapter 9 pages 9.47 to 9.57 describe the standard technique of hybridization of radiolabeled probes to immobilized nucleic acids. A copy of the relevant pages is included with this response. This book discusses stringent conditions and methods to reduce background binding. Page 9.50 (note 9) references a method of calculating the temperature conditions which are very important in hybridizing under stringent conditions. Pages 9.52-9.55 disclose a specific procedure under which stringent conditions are used. This *Molecular Cloning* text is considered to be the book molecular biologists (any many other types of scientists) reference when they need information on a standard molecular biology procedure. Thus, Applicant submits that the currently pending claims which use the word "stringent conditions" are clear and distinctly claim Applicant's invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112 is respectfully requested.

**Claim Rejections - 35 U.S.C. §102**

Claim 10 is rejected under 35 U.S.C. §102(b) as anticipated by Hiatt, et al (US 4,801,540). Applicants submit that the currently amended claim 10 is not anticipated by Hiatt. Hiatt discloses a polynucleotide sequence of tomato polygalacturonase. Hiatt does not disclose a polynucleotide which encodes for a codeinone reductase enzyme as claimed by Applicant. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

Claims 46-48 are rejected under 35 U.S.C. §102(b) as anticipated by Hiatt, et al (US 4,801,540), Welle, et al, van der Krol, et al, and Tsukaya, et al. Applicant's cancellation of claims 46-48 has rendered Examiner's rejection moot.

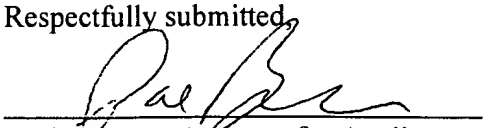
**Conclusion**

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that currently pending claims 1-2, 4-19, 43-45, 59, and 63-67 are in condition for allowance, and such action is respectfully requested. Should there be any fees required at this time, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 10-0750.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Dated: August 30, 2006

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